

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s)	: Mary Darlene Temple	Group Art:	not yet assigned
Serial No.	: not yet assigned	Examiner:	not yet assigned
Filed	: herewith		
For	: APPARATUS AND METHOD FOR DELIVERY OF MEDICATION		

HON. ASSISTANT COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is filed in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The submission of this Information Disclosure Statement shall not be construed as a representation that a search has been made or that no other items than those identified herein exist. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

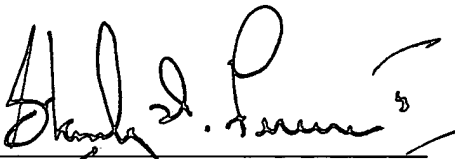
1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:  
  
A:  
B:
2. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☐ Any copy of the items listed on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in the prior ☐ Continuation, ☐ Divisional or ☐ Continuation-In-Part application under 37 C.F.R. § 1.60, U.S. Serial No. \_\_\_\_\_, filed \_\_\_\_\_.
4. ☒ No fee is due under 37 C.F.R. § 1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:

- ☒ 37 C.F.R. § 1.97(b)(1), within three months of the filing date of the above-identified application.
- ☐ 37 C.F.R. § 1.97(b)(2), within three months of the date of entry into the national stage as set forth in § 1.491 in an international application.
- ☐ 37 C.F.R. § 1.97(b)(3), before the mailing date of a first Office action on the merits.
5. ☐ No fee is due under 37 C.F.R. § 1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. § 1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the verifications pursuant to 37 C.F.R. § 1.97(e) set forth in paragraph 9 below.
6. ☐ A fee is due under 37 C.F.R. § 1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. § 1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):
- ☐ A check in the amount of \$240.00 is enclosed in payment of the fee.
7. ☐ A fee is due under 37 C.F.R. § 1.17(i) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. § 1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:
- a. one of the certifications pursuant to 37 C.F.R. § 1.97(e) set forth in paragraph 9 below; and
  - b. the attached petition requesting consideration of this Information Disclosure Statement; and
  - c. the fee due under 37 C.F.R. § 1.17(i) which is paid as set forth in paragraph 10 below.
8. ☐ A fee is due under 37 C.F.R. § 1.17(i) for this Information Disclosure Statement since it is being filed in compliance with:
- a. ☐ 37 C.F.R. § 1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue.
  - b. ☐ 37 C.F.R. § 1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue.
  - c. ☐ The fee due under 37 C.F.R. § 1.17(i) is paid as set forth in paragraph 10 below.

9. ☐ I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- ☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
10. ☐ A check in the amount of \$130.00 is enclosed in payment of the fee due under 37 C.F.R. § 1.17(i).

Respectfully submitted,

ERENCE & ASSOCIATES

By:   
Stanley D. Ference III  
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Dated: 2 December 2003

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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	Unassigned
				Filing Date	November 25, 2003
				First Named Inventor	Mary Darlene TEMPLE
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	671.001
Sheet	1	of	2		

[illegible][illegible]

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.**

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	Unassigned
				Filing Date	November 25, 2003
				First Named Inventor	Mary Darlene TEMPLE
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
Sheet	2	of	2	Attorney Docket Number	671.001

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		American Diabetes Association, "Eye Care and Retinopathy", <a href="http://www.diabetes.org/info/complications/retinopathy/default.jsp">http://www.diabetes.org/info/complications/retinopathy/default.jsp</a>	
		National Diabetes Information Clearinghouse, "National Diabetes Statistics", <a href="http://www.niddk.nih.gov/health/diabetes/pubs/dmstats/dmstats.htm">http://www.niddk.nih.gov/health/diabetes/pubs/dmstats/dmstats.htm</a>	
		M. MALONE, "Comparison Between Methods for Determination of Glycosylated Hemoglobin A1C Levels in Subjects with Normal and Atypical Hemoglobins", Dept. of Pathology, Univ. of Pittsburgh School of Medicine, Pgh. PA 15213. <a href="http://path.upmc.edu/showcase/posters/alc.htm">http://path.upmc.edu/showcase/posters/alc.htm</a>	
		A. ARIES, Ph.D., "Effective Color Contrast", Arlene R. Gordon Research Institute, Lighthouse International, 111 E. 59th St., NY, NY 10022-1202, <a href="http://www.lighthouse.org/color_contrast.htm">http://www.lighthouse.org/color_contrast.htm</a>	
		D.W. GUTHRIE, R.N., "The Diabetes Sourcebook", 5th Edition, McGraw-Hill, pp.15-29, 58-59, 100-115.	
		Diabetes Forum, "Diabetes Mellitus and Insulin Storage", <a href="http://www.diabetesforum.net/eng_treatment_DM_Insulin_storage.htm">http://www.diabetesforum.net/eng_treatment_DM_Insulin_storage.htm</a>	
		B.A. CARLISLE et al., "101 Medication Tips for People with Diabetes", Chapters 4-6, pp.41-65, American Diabetes Association.	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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